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R 55402

EXAMINER

WALSH, S

18N2/1122

ART UNIT

PAPER NUMBER

23

WENDY M LEE
GENENTECH INC
460 POINT SAN BRUNO BOULEVARD
SOUTH SAN FRANCISCO CA 94080-4990

1812

DATE MAILED:

11/22/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 4/4/95 and 7/13/95 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 3, 5, 7, 22, 26 and 28-35 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 3, 5, 7, 22, 26 and 28-35 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

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1. The substitute specification and amendment filed 13 July 1995 have been entered.
2. Applicant's arguments filed 13 July 1995 have been fully considered but they are not deemed to be persuasive.

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3. The drawings remain objected to for the reasons of record. Correction is required.

Applicants are reminded that the Brief Description of the Drawings should be amended to refer to Panel A and Panel B in Figure 1. Applicants are reminded that when a formal Figure 13 is prepared, if the sequence requires separate sheets, the separate sheets should be labeled as subfigures: Fig. 13A, Fig. 13B, etc., and the Brief Description of the Drawings should be amended accordingly.

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Applicants' intent to defer correction is noted. However, the correction for the Brief Description of Figure 1 should be made prior to allowance because the application could not be passed to issue as it stands. The description of Figure 13 can be deferred until the formal Figure 13 is prepared because of the likelihood of change.

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4. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5 Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

10 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

15 Claims 3, 5, 7, 22 and 26 are again rejected, and new claims 28-35 are now rejected under 35 U.S.C. § 103 as being unpatentable over Yamamoto et al(AJ) or Coussens et al(AL) each in view of Weber et al, Dull et al. or Dower et al., for reasons of record.

20 Applicants argue that in order to obtain the protein as recited in the claims it was necessary to remove more than just the transmembrane portion, and that the discovery of this problem makes the claimed protein unobvious. The rejection of record included the embodiment wherein truncation is done about 8 residues upstream from the transmembrane domain. The basis for rejection was that this truncation point was obvious over the disclosure by Yamamoto et al. that the second cysteine cluster in the extracellular domain ends at that point, and that the stabilizing influence of the cluster would have
25 desirable to maintain in a truncated form of HER2. That would have been immediately appreciated by one of ordinary skill in this art. Applicants argue that removal of the 8 amino acids was critical in view of the problem they encountered with truncating at the transmembrane domain, and that the artisan would have had no motivation to truncate at

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any position other than at the immediate end of the transmembrane domain. However, the structural information disclosed by Yamamoto et al. suggests that as long as the end of the second cysteine cluster was included, the extracellular domain would have been stable. Accordingly, truncation at any position between the transmembrane domain and the end of the cysteine cluster would have been obvious. The fact that Applicants discovered that not all of those obvious compounds may have been soluble does not negative the suggestion from Yamamoto et al.'s structure that at least the end of the second cysteine cluster would have been a reasonable truncation point. Applicants also argue that the extreme 3' end of Yamamoto et al.'s full length sequence is different from the extreme 3' end of Applicants' full length HER2 sequence. But the extreme 3' end is not germane to the claims because it encodes not the extracellular domain but the intracellular domain which is to be removed; that is, the extreme 3' end is irrelevant to the obviousness of the claimed compositions because it is not part of the compounds claimed. Applicants argue that Weber et al. taught away from the instant application by adding an amino acid to the C-terminus, but Weber et al. was relied upon for teaching a soluble truncated receptor, not for the amino acid sequence. Further, it should be noted that Applicants' claims with the open "comprising" language have no basis for distinguishing on the basis of extra amino acids. Applicants argue that Dower et al.'s IL-1 receptor is much smaller than Applicants' receptor, that Dower et al. obtained two different glycosylation forms, and that Dower et al. truncated their receptor three residues upstream of the transmembrane domain, and that Dower et al. could not have been predictive for Applicants' HER2. It is not seen how about 3 residues and about 8 residues is a non-obvious difference, especially in light of

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Yamamoto et al.'s disclosure that the second cysteine cluster, an undisputed stabilizing feature, ends about 8 residues from the transmembrane domain. Glycosylation varies in proteins depending on the host cell; this issue is not germane to the instant claims which recite no glycosylation limitations. Although Applicants assert that the size difference
5 between Dower et al.'s about 550 residues and the instant about 624 residues means it is Much smaller, there are no reasons advanced to consider that it has a bearing on what would have been reasonably expected.

5. The prior art made of record and not relied upon is considered pertinent to
10 applicant's disclosure. Weber et al(R') and Basu et al(S') each disclose soluble truncated EGF receptor forms analogous to the soluble, truncated HER2 forms claimed. Because of the known close relation between EGF receptor and HER2, each of Weber et al. and Basu et al. is deemed to support the rejection of record.

15 6. Applicant's amendment necessitated the new grounds of rejection. Accordingly,
THIS ACTION IS MADE FINAL. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

20 A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED
25 STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stephen Walsh whose telephone number is (703) 308-2957. The Examiner can normally be reached on Monday-Friday from 8:00AM to 4:00PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Garnette D. Draper, can be reached on (703) 308-4232.

Papers related to this application may be submitted to Group 1800 in Crystal Mall 1 by facsimile transmission, in conformity with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The FAX phone number for Art Unit 1812 is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stephen Walsh
Stephen Walsh, Ph.D.
Primary Examiner
Group 1800

SW
November 10, 1995